REMARKS

Applicants respectfully request entry of the foregoing and continued examination of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.114, and in light of the remarks which follow.

As stated in the Office Action Summary, claims 1-8 are pending. Claims 1 and 7-8 are amended herein to recite asthma bronchiole as the claimed condition. Basis for the amendments may be found throughout the specification and claims as-filed, especially at page 1, line 32 to page 2, line 6.

Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present amendment.

Applicants note with appreciation that, as indicated in the Advisory Action of March 30, 2005, the rejections pursuant to 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 112, second paragraph, have been withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1-4 and 7-8 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Doi, Koji (WO 9831343), Bjerkec, and van der Molen for the reasons of record. The Office maintains that it would have been obvious to employ loteprednol etabonate in combination with reproterol, salmeterol, or formoterol in a pharmaceutical composition method for the treatment of allergies and/or airway disorders for simultaneous, sequential or separate administration. Applicants traverse.

First, it is noted that the present claims, as amended herein, are directed to a pharmaceutical composition and methods for treating asthma bronchiale.

The Office states that it would be obvious to the skilled artisan to combine two compositions for the treatment of the same condition, as disclosed in the cited references, to create a third composition for the treatment of the same condition. However, the primary reference, Doi, is directed to the use of loteprednol etabonate for the treatment of inflammatory or allergic disease only. Asthma bronchiale or even related conditions are not disclosed in Doi as being treated by loteprednol. Instead, classical steroids are disclosed for the treatment of asthma.

Applicants again note the significant differences between classical steroids and loteprednol. Classic steroids cannot be extrapolated to soft steroids, such as loteprednol, as there are different mechanistic properties between these two groups of steroids. Further, loteprednol exhibits less side effects, improved therapeutic breadth and an overadditive therapeutic effect in combination with the disclosed ÿ2-adrenoreceptor agonists. However, none of the references disclose any of these advantages for loteprednol, whether used alone or in combination with a ÿ2-adrenoreceptor.

Thus, in light of the present amendments and above remarks, the cited references do not disclose two compositions to be used to treat the conditions of the present claims, which may be combined to create a third composition for the treatment of the same conditions. Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: May 17, 2005

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